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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,351	10/31/2003	Ronald James Jandacek	9129L	2523

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THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL BUSINESS CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,351	JANDACEK ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *37-70 and 72-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/06/04; 6/17/04 & 5/25/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Claims 1-36 and 71 are pending in this office action.

Claims 37-70 and 72-78 are withdrawn as non-elected specie.

Response to Restriction Election

Applicant's election with traverse of Group I claims 1-36 and 71 in the reply filed on 4/7/06 is acknowledged. Claims 37-70 and 72-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected specie, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/7/06. The traversal is on the ground(s) that

> The Applicants respectfully traverse the restriction and election requirements. The Applicants assert that if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though the Examiner is of the viewpoint that the claims should otherwise be restricted. See MPEP 803. The Examiner states that groups I and II are related as product and process of use, groups I and III are related as product and process of use, groups IV and I are related as product and process of use, groups II and III are related as product and process of use, groups II and IV are related as product and process of use, and groups III and IV are related as product and process of use.

. This is not found persuasive because The Groups have acquired a separate status in the art by their recognized, divergent subject matter. The searches required for each Group are not co-extensive resulting in an undue burden to the Examiner. Each Group is capable of supporting a separate patent. Restriction for examination purposes as indicated is proper. Because these inventions are independent or distinct for the reasons given

above and the inventions require a different field of search (see MPEP j 808.02), restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 16, 2004, June 17, 2004 and May 25, 2005 have been received and acknowledged.

Abstract

The abstract of the disclosure is objected to because it contains more than two paragraphs. Also, the abstract is Therefore one of ordinary skill in the art would have known to combine long, contains more than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-10, 13-14, 16, 19-20, 22 and 25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "atleast about" in claims 1-10, 13-14, 16, 19-20, 22 and 25 is a relative term which renders the claim indefinite. The term " atleast about " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the

scope of the invention. The atleast is interpreted as there has to be a minimum of a certain amount, while the about is interpreted to be anywhere within for example about 2% means from anywhere from 0.1-2%.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

I. Claims 1-6, 8,10-11and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by de Smidt et al. US 6,703,369 B1.

With regards to claim 1 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and (ii) a lipase inhibitor (see col. 1 lines 46+) wherein the ratio of the stiffening agent is at least 4.5:1 (see col. 4, lines 38-65). For example if the stiffening agent present in an amount of 45% and the lipase inhibitor present is 10%, the ratio therefor is 4.5:1. Thus claims 2 and 8 are encompassed by the teaching.

As to claim 3, the stiffening agent is a fatty acid (see abstract) and a pharmaceutical salt as in claim 4(see col. 2, lines 11-25), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 5, 6 and 11.

Further, de Smidt et al. teach, with regards to claim 10 the percentage of the stiffening agent is about 0.8% is anticipated (see col. 4 lines 38-40). Thus claim 21 is anticipated.

II. Claims 13-19 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by de Smidt et al. US 6,703,369 B1.

With regards to claim 13 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and (ii) a lipase inhibitor (see col. 1 lines 46+) wherein the ratio of the stiffening agent is at least 2:1 (see col. 4, lines 38-65). For example if the stiffening agent present in an amount of 10% and the lipase inhibitor present is 10%, the ratio therefor is 1:1. Thus claims 14, 16 and 19 are encompassed by the teaching.

As to claim 15, the stiffening agent is a fatty acid (see abstract), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 17, 18, and 23.

Further, de Smidt et al.teach, with regards to claim 21 the percentage of the stiffening agent is about 0.8% is anticipated (see col. 4 lines 38-40).

III. Claims 25-27,and 29-30 are rejected under 35 U.S.C. 102(e) as being anticipated by de Smidt et al. US 6,703,369 B1.

With regards to claim 25 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and (ii) a lipase inhibitor (see col. 1 lines 46+) wherein the stiffening agent is at least 5% (see col. 4, lines 38+) and from 5% to about 90% as in claim 27 is inclusive of the teaching (see col. 4, lines 38+)

As to claim 26, the stiffening agent is a fatty acid (see abstract), wherein the composition comprises a lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 29 and 30.

IV. Claims 31-33 and 35-36 are rejected under 35 U.S.C. 102(e) as being anticipated by de Smidt et al. US 6,703,369 B1.

With regards to claims 31 and 35 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and a lipase inhibitor (see col. 1 lines 46+) as in claim 35, wherein the stiffening agent is at least 5% (see col. 4, lines 38-65) as in claim 33.

As to claim 32, the stiffening agent is a fatty acid (see abstract), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 35 and 36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

With regards to claim 1 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and (ii) a lipase inhibitor (see col. 1 lines 46+) wherein the ratio of the stiffening agent is at least 4.5:1 (see col. 4, lines 38-65). For example if the stiffening agent present in an

amount of 45% and the lipase inhibitor present is 10%, the ratio therefor is 4.5:1. Thus claims 2 and 8 are obvious variation of the teaching.

As to claim 3, the stiffening agent is a fatty acid (see abstract) and a pharmaceutical salt as in claim 4(see col. 2, lines 11-25), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 5, 6 and 10.

Further, de Smidt et al.teach, with regards to claim 10 the percentage of the stiffening agent is about 0.8% would have been obvious (see col. 4 lines 38-40).

Maeder et al. also teach having a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines 7-21), wherein the fatty acid is selected from behenic acid (see col. 5, lines 43+) as in claim 12.

The instant method differs from the de Smidt et al. teaching only in the specific range of the lipase to stiffening ratio as in claim 7, nor the limitations of claim 12.

However, the determination of a ratio having the optimum index is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine the optimum amounts to get the maximum effect, hence the reference makes obvious the instant invention.

Also, one of ordinary skill would have combined the teachings of de Smidt et al. with that of Maeder et al. choose the fatty acid behenic acid and expect a successful result in doing so because both cited references teaches using fatty acid and substituting the specific fatty acid of Maeder et al would have been obvious.

II. Claims 13-24 are rejected under 35 U.S.C. 103(a) as being as unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

With regards to claim 13 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and (ii) a lipase inhibitor (see col. 1 lines 46+) wherein the ratio of the stiffening agent is at least 2:1 (see col. 4, lines 38-65). For example if the stiffening agent present in an amount of 10% and the lipase inhibitor present is 10%, the ratio therefor is 1:1. Thus claims 14,16 and 19 are encompassed by the teaching.

As to claim 15, the stiffening agent is a fatty acid (see abstract), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 17, 18, and 23.

Further, de Smidt et al.teach, with regards to claim 22 the percentage of the stiffening agent is about 0.8% is obvious (see col. 4 lines 38-40).

Maeder et al. also teach having a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines 7-21), wherein the fatty acid is selected from calcium sterate (see col. 5, lines 37-67+) as in claims 13(ii) and 24.

The instant method differs from the de Smidt et al. teaching only in the specific range of the lipase to stiffening ratio as in claim 20-21, nor the limitations of claim 24.

However, the determination of a ratio having the optimum index is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine the optimum amounts to get the maximum effect, hence the reference makes obvious the instant invention.

Also, one of ordinary skill would have combined the teachings of de Smidt et al. with that of Maeder et al. choose the fatty acid calcium stearate and expect a successful result in doing so because both cited references teaches using fatty acid and substituting the specific fatty acid of Maeder et al. would have been obvious.

III. Claims 25-30 are rejected under 35 U.S.C. 103(a) as being as unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

With regards to claim 25 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and (ii) a lipase inhibitor (see col. 1 lines 46+) wherein the stiffening agent is at least 5% (see col. 4, lines 38+) and from 5% to about 90% as in claim 27 is inclusive of the teaching (see col. 4, lines 38+)

As to claim 26, the stiffening agent is a fatty acid (see abstract), wherein the composition comprises a lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 29 and 30.

Maeder et al. also teach having a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines

7-21), wherein the fatty acid is selected from calcium sterate (see col. 5, lines 37-67+), behenic acid (see col. 5, lines 43+).

The instant method differs from the de Smidt et al. teaching only where the specific fatty acid is selected from calcium stearate, behenic acid and mixtures thereof.

One of ordinary skill would have combined the teachings of de Smidt et al. with that of Maeder et al. choose the fatty acid calcium stearate and expect a successful result in doing so because both cited references teaches using fatty acid and substituting the specific fatty acid of Maeder et al. would have been obvious.

IV. Claims 31-36 and 71 are rejected under 35 U.S.C. 102(e) as being as unpatentable over de Smidt et al. US 6,703,369 B1 in taken with Maeder et al. US 6,730,319 B2 in view of Hug et al US 6,358,522.

With regards to claim 31 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C_{12-20}) (see col. 3, line 60), with a melting point of 37°C and a lipase inhibitor (see col. 1 lines 46+) as in claim 35 and 71, wherein the stiffening agent is at least 5% (see col. 4, lines 38-65) as in claim 33.

As to claim 32, the stiffening agent is a fatty acid (see abstract), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 35 and 36.

Maeder et al. also teach having a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines

7-21), wherein the fatty acid is selected from behenic acid (see col. 5, lines 43+) as in claim 31(ii).

Hug et al teach a pharmaceutical compositions containing an inhibitor of gastrointestinal lipases, one (or more) additive(s) of the group consisting of substantially non-digestible food grade thickeners and emulsifiers, and excipients (see abstract).

One of ordinary skill would have combined the teachings of de Smidt et al. with that of Maeder et al. choose the fatty acid calcium stearate and expect a successful result in doing so because both cited references teaches using fatty acid and substituting the specific fatty acid of Maeder et al. would have been obvious.

Further on of skill would be motivated to combine the teachings of de Smidt et al. taken with Maeder et al in view of Hug et al and for the absorbtion of oil as taught by Hug et al.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H. Marschel 6/26/06

SVG
6/13/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER